

### III. Remarks

Applicants affirm their election with traverse of Group I, peptide sequence SEQ ID NO. 1. Further, Applicants have corrected a typographical error in Claim 15 such that the scope of Claim 15 and that of the allowed product claims of U.S. Pat. No. 6,184,204 are the same. Applicants respectfully request that the Examiner consider Claim 15.

Claims 2, 3, 7, and 13-14 stand rejected under 35 USC §102(b) as being anticipated by an article to Hakala. The Examiner contends that the article to Hakala discloses the sequence of the full length HC gp-39 protein in a pharmaceutical composition with a pharmaceutically acceptable carrier. Applicants have amended Claims 2, 13, and 14 to specify that the language is "consisting of" and exclude the claimed peptide from the full length sequence. Applicants respectfully request reconsideration of the rejection.

Claim 11 stands rejected under 35 USC §103 as being unpatentable over Hakala et al. The Examiner contends that the claimed subject matter differs from Hakala by only the recitation of a kit. Applicants respectfully request reconsideration of the rejection in light of this response. Applicants respectfully add that New Claim 18 has been added that is the same as the scope of former Claim 11. Accordingly, Applicants respectfully request that the Examiner consider Claim 18 when considering the arguments presented herein.

It has long been the law that an obviousness determination requires that an Examiner perform an analysis of (1) the scope and content of prior art, (2) the differences

between the prior art and the claims at issue, (3) the level of ordinary skill in the art, and (4) objective evidence of non-obviousness. Here, the Examiner has not analyzed any of these criteria. Here, the Examiner only states that "A kit for..." does not convey any patentable weight to the actual components of the kit itself.

It is well established that "[A] claim preamble has the import that the claim as a whole suggests for it." *Bell Comm. Res., Inc. v. Vitalink Comm., Inc.*, 55 F. 3d 615, 620 (Fed. Cir. 1995). Here, the preamble states an intended purpose and will act as a limitation. *See Rowe v. Dror*, 112 F. 3d 473, 478 (Fed. Cir. 1997). Applicants have positively claimed a test kit. The limitation of a test kit is a patentable distinction.

As to the obviousness rejection, "[o]bviousness is a question of law based on findings of underlying facts relating to the prior art, the skill of the artisan, and objective considerations." *See Graham v. John Deere Co.*, 383 U.S. 1, 17, (1966). To establish a *prima facie* case of obviousness based on a combination of the content of various references or to modify an existing reference, there must be some teaching, suggestion or motivation in the prior art to make the specific combination that was made by the applicant. *In re Raynes*, 7 F.3d 1037, 1039 (Fed. Cir. 1993); *In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992).

Obviousness cannot be established by hindsight combination to produce the claimed invention. *In re Gorman*, 933 F.2d 982, 986 (Fed. Cir. 1991). As discussed in *Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1143 (Fed. Cir. 1985), it is the prior art itself, and not the applicant's achievement that must establish the obviousness of the combination. Here, the art cited by the Examiner does not contain any reference to a kit. Moreover, the addition of a kit is a limitation that does add patentable significance, as

none of the prior art contains a test kit for use in the detection of activated autoreactive T cells, comprising one or more peptides consisting of 16 to 55 amino acid residues, comprising at least one of the amino acid sequences YKLVCYYTSWSQYREG (SEQ ID NO: 1), YTSWSQYREGDGSCFP (SEQ ID NO: 2), LDRFLCTHIIYSFANI (SEQ ID NO: 5), THIIYSFANISNDIUD (SEQ ID NO: 6), PNLKTLLSVGGWNFGS (SEQ ID NO: 12), NTQSRRTFIKSVPF (SEQ ID NO: 16), TFIKSVPPFLRTHGFD (SEQ ID NO: 17), PPFLRTHGFDGLDLAW (SEQ ID NO: 18), HGFDGLDLAWLYPGRR (SEQ ID NO: 19), DLAWLWYGRDKQHFT (SEQ ID NO: 20), TIDSSYDIAKISQHLD (SEQ ID NO: 28), DIAKISQHLDLISIMT (SEQ ID NO: 29), QHLDLISIMTYDFHGA (SEQ ID NO: 30), SPLFRGQEDASPDRFS (SEQ IS NO: 34), DYAVGYMLRLGAPASK (SEQ ID NO: 37), MLRLGAPASKLVMGIP (SEQ ID NO: 38), PASKLVMGIPTFGRSF (SEQ ID NO: 39, GTLAYYEICDFLRGAT (SEQ ID NO: 46), EICDFLRGATVHRTLG (SEQ ID NO: 47), RGATVHRTLGQQVPYA (SEQ ID NO: 48), VKSKVQYLKDRQLAGA (SEQ ID NO: 53), YLKDRQLAGAMVWALD (SEQ ID NO: 54), LAGAMVWALDLDDFQG (SEQ ID NO: 55), WALDLDDFQGSFCGQD (SEQ ID NO: 56) and DFQGSFCGQDRLRFPLT (SEQ ID NO: 57). Accordingly, Applicants respectfully request reconsideration of rejection.

“When obviousness is based on a single prior art reference, there must be a showing of a suggestion or motivation to modify the teachings of that reference.” *See B.F. Goodrich Co. v. Aircraft Breaking Sys. Corp.*, 72 F.3d 1577, 1582 (Fed. Cir. 1996). Here, there is no suggestion or showing. The identification of the full length sequence cannot be said to teach or suggest a test kit for use in the detection of activated autoreactive T cells, comprising one or more peptides consisting of 16 to 55 amino acid

residues, comprising at least one of the amino acid sequences YKLVCVYTSWSQYREG (SEQ ID NO: 1), YTSWSQYREGDGSCFP (SEQ ID NO: 2), LDRFLCTHITYSFANI (SEQ ID NO: 5), THIYSFANISNDHID (SEQ ID NO: 6), PNLKTLSSVGGWNFGS (SEQ ID NO: 12), NTQSRRTFIKSVPPFL (SEQ ID NO: 16), TFIKSVPFLRTHGFD (SEQ ID NO: 17), PPFLRTHGFDGLDLAW (SEQ ID NO: 18), IIGFDGLDLAWLYPGRR (SEQ ID NO: 19), DLAWLYPGRRDKQHFT (SEQ ID NO: 20), TIDSSYDIAKISQHLD (SEQ ID NO: 28), DIAKISQHLDIFISIMT (SEQ ID NO: 29), QHLDIFISIMTYDFHGA (SEQ ID NO: 30), SPLFRGQEDASPRDRFS (SEQ ID NO: 34), DYAVGYMLRLGAPASK (SEQ ID NO: 37), MLRLGAPASKLVMGIP (SEQ ID NO: 38), PASKLVMGIPTFGRSF (SEQ ID NO: 39), GTLAYYEICDFLRGAT (SEQ ID NO: 46), EICDFLRGATVHRTILG (SEQ ID NO: 47), RGATVHRTLGQQVPYA (SEQ ID NO: 48), VKSKVQYLKDRQLAGA (SEQ ID NO: 53), YLKDRQLAGAMVWALD (SEQ ID NO: 54), LAGAMVWALDLDDFQG (SEQ ID NO: 55), WALDLDDFQGSFCGQD (SEQ ID NO: 56) and DFQGSFCGQDRLRFPLT (SEQ ID NO: 57).

Our case law makes clear that the best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis is rigorous application of the requirement for a showing of the teaching or motivation to combine prior art references.

*See, e.g., C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1352, 48 USPQ2d 1225, 1232 (Fed. Cir. 1998) (describing teaching or suggestion or motivation to combine as an essential evidentiary component of an obviousness holding); *In re Rouffet*, 149 F.3d 1350, 1359 (Fed. Cir. 1998) (the reasons one of ordinary skill in the art would have been motivated to modify the references must be explicitly stated); *In re Fritch*, 972 F.2d

1260, 1265 (Fed. Cir. 1992) (examiner can satisfy burden of obviousness in light of combination only by showing some objective teaching leading to the combination); *In re Fine*, 837 F.2d 1071, 1075 (Fed. Cir. 1988) (evidence of teaching or suggestion essential to avoid hindsight). Strict adherence to the factual predicate of obviousness is required. *See Graham*, 383 U.S. at 18.

The Examiner has supplied missing patentable matter. However, the Federal Circuit has made clear that rarely will the skill in the art component operate to supply missing knowledge or prior art to reach an obviousness judgment. *See W.L. Gore & Assocs., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1553 (Fed.Cir.1983) ("To imbue one of ordinary skill in the art with knowledge of the invention in suit, when no prior art reference or references of record convey or suggest that knowledge, is to fall victim to the insidious effect of a hindsight syndrome wherein that which only the inventor taught is used against its teacher."). Skill in the art does not act as a bridge over gaps in substantive presentation of an obviousness case, but instead supplies the primary guarantee of objectivity in the process. *See Ryko Mfg. Co. v. Nu-Star, Inc.*, 950 F.2d 714, 718 (Fed. Cir. 1991). Accordingly, as this response illustrates, the Examiner has not established a *prima facie* case of obviousness. Therefore, Applicants respectfully request reconsideration of the rejection.

#### IV. Conclusion

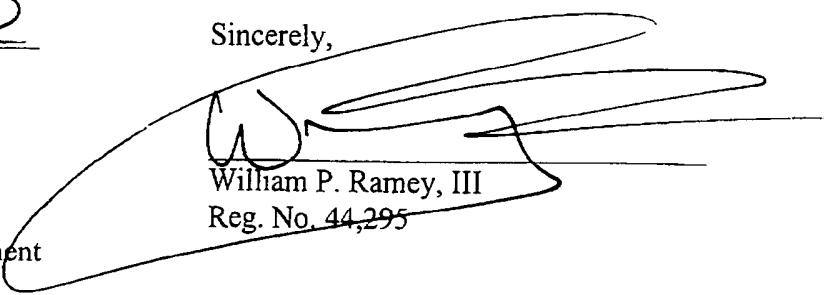
Applicants respectfully elect Group I with traverse. Applicants respectfully request reconsideration of the rejection in light of this response. The application is believed in a condition for allowance and Applicants respectfully request such action.

Please call the below undersigned attorney for any assistance in securing allowance of this application or if the Examiner feels that an interview would further the prosecution of this case. Please charge deposit account number 02-2334 for any required fees.

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7/8/02

Sincerely,

  
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